Brimms Inc

Brimms Laboratories • Shield • KazooCo



June 14, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 99N-0035
Medical Devices; Reclassification of 38
Preamendments Class III Devices into Class II

Dear Sir or Madam:

The following comments are submitted by Brimms Inc. (Brimms) concerning the Food and Drug Administration's (FDA's) proposed rule to reclassify over-the-counter (OTC) denture cushions and pads. See 64 Fed. Reg. 12774, 12791 (March 15, 1999).

Brimms is a small, privately held company that manufactures a variety of consumer products, including OTC denture-related devices. One of these devices is Denturite®, a soft plastic flow-formed denture cushion intended for short-term use.

The proposed rule would reclassify OTC denture cushions and pads identified in 21 C.F.R. § 872.3540 as class II. The special controls to which these devices would be subject are: (1) International Standards Organization's ISO 10993 "Biological Evaluation of Medical Devices Part I: Evaluation and Testing"; and (2) FDA's "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits" (hereinafter Guidance Document).

Brimms supports the agency's proposal to reclassify OTC denture cushions and pads. However, with respect to OTC flow-formed synthetic temporary denture surfaces, Brimms believes that class I classification is sufficient to provide reasonable assurance of the safety and effectiveness of these devices. This was the recommendation of FDA's Dental Products Advisory Panel, which reviewed Brimms' petition to reclassify Denturite®,[1] and FDA has not articulated a reasoned basis for rejecting this recommendation. Brimms therefore urges FDA to reclassify Denturite® and denture cushions or pads with similar properties as class I.

[1] Food and Drug Administration, Dental Products Advisory Panel Meeting, Reclassification of OTC Flow-Formed Synthetic Temporary Denture Surfaces, February 12, 1997, at 174 (hereinafter "Panel Meeting").

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Brimms also believes that the warning statement recommended by FDA in its guidance document for the labeling of OTC denture pads and cushions, which tracks the language of 21 C.F.R. § 801.405, inaccurately describes the risks associated with use of the product. Brimms urges FDA to amend the warning statement in the manner the company has suggested below.

## I. BACKGROUND

Denturite® flow-formed temporary denture surface is a soft, synthetic elastomer that flows freely to conform precisely to the contours of the gums and dentures. It is created by the consumer by mixing a premeasured amount of polymerized polyethyl methacrylate powder and a solution comprising approximately 76 percent plasticizer, 19 percent ethyl alcohol, and five percent polyvinyl acetate as a softener. The viscous liquid formed by mixing these ingredients is applied to denture surfaces. It is designed to flow freely between the denture and the gums for a period of several minutes under bite pressure until the mixture sets to form an elastomer gel. The liquid fills areas where there is a poor fit between gums and denture and flows out of areas where there is a closer apposition.

After the material forms to fit, the denture is removed and any excess material can be trimmed from the denture edges. The entire device can be removed from the dentures easily by soaking them in warm water.

## II. DENTURITE® HAS BEEN SAFELY MARKETED FOR ALMOST FOUR DECADES

Denturite® has been marketed as a temporary denture surface for over 38 years. In four decades of clinical use, approximately 25 million units have been distributed commercially and used in the U.S. In that time period virtually no evidence of significant or unreasonable risk to health associated with the use of the device has been reported to the manufacturer. Between 1989 and 1996 Brimms distributed approximately 6.5 million units of the product. Brimms' complaint rate during this time period was one per 255,000 units sold. Of these reports, none showed evidence of serious injury. These data clearly demonstrate the safety and effectiveness of the product.

## III. FDA HAS REPEATEDLY IGNORED BRIMMS' SAFETY DATA

Brimms has submitted data to FDA demonstrating the safety of Denturite® on several occasions. FDA has repeatedly failed to acknowledge these data and has continued to lump Denturite-type devices with other denture cushions and pads, notwithstanding data submitted by Brimms demonstrating that Denturite® does not pose the health risks that FDA has attributed to some denture cushions and pads.

In 1980, FDA published a proposal to classify dental devices. 45 Fed. Reg. 85962 (Dec. 30, 1980). Brimms submitted to the Dental Device Classification Panel the results of toxicity studies that established the safety of characteristic ingredients and the results of a clinical study that demonstrated that this type of device presents no unreasonable potential risk to the user. These studies were submitted to FDA as attachments to comments filed by Brimms, in which the company urged FDA to establish a separate classification identifying OTC flow-formed temporary denture surfaces and that it classify these devices into class I.[2]

When it issued its final dental device classification rule in 1987, 52 Fed. Reg. 30082 (Aug. 12, 1987), FDA designated all OTC denture cushions and pads as class III, with the exception of OTC wax-impregnated cotton cloth cushions intended for one-day use, which it designated as class I. In the preamble to the reclassification rule, FDA asserted that class III was appropriate for all other denture cushions or pads, as well as for denture reliners and repair kits. Citing the findings of the Dental Devices Panel from 1980, FDA stated:

> Use of these devices may cause an improper vertical dimension of a denture which may result in increased biting forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The long-term irritation of oral tissue caused by an incorrect vertical dimension also could cause formation of carcinomas.

52 Fed. Reg. at 30092.

FDA did not address, and apparently failed to consider, the data submitted by Brimms establishing the safety and effectiveness of temporary flow-forming denture surface devices. In contrast, FDA acknowledged the studies submitted by a manufacturer of wax-impregnated cotton cushions and classified these products as category I based on these data. Id.

On April 19, 1994, FDA issued a document setting forth the agency's strategy for implementing the provisions of the Safe Medical Devices Act of 1990 (SMDA). See 59 Fed. Reg. 23731 (May 6, 1994) (announcing availability of document). OTC denture cushion and pads described in 21 C.F.R. § 872.3540(b)(2) were included in "High Priority Group 3."[3] These devices were not eligible for reclassification, and FDA stated that it intended to require the submission of premarket approval applications (PMAs) in the near future. Brimms submitted comments arguing that Denturite-type devices did not belong in this category because they had

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[2] Comments of Brimms Inc., submitted to Docket No. 78N-2830, Proposed Classification of Dental Devices, April 1, 1981.

[3] FDA stated that High Priority Group 3 devices were those for which "significant issues of safety and/or effectiveness are not being resolved or, to the best of FDA's knowledge, have little possibility of being resolved. . . ."

been established to be safe and effective, and were therefore eligible for reclassification.[4] Brimms included with its submission both clinical and toxicological data supporting its view.

In July 1995, FDA published a proposed rule to require the filing of a PMA or notice of completion of product development protocol (PDP) for OTC denture cushions and pads and OTC denture repair kits. 60 Fed. Reg. 35713 (July 11, 1995). FDA reiterated its belief that these products posed a health risk and that there "is no recent evidence in the published scientific literature to suggest that these risks are no longer relevant." 60 Fed. Reg. at 35715. FDA did not discuss the data that had been submitted by Brimms in 1994.

The 1995 proposal also announced the opportunity to submit requests for changes in classification based on "new information." In response, Brimms submitted a petition requesting reclassification of OTC flow-formed synthetic temporary denture surfaces to class I.[5] On February 12, 1997, the Dental Products Advisory Panel voted to recommend class I classification for these devices. The Advisory Panel findings and conclusions are discussed in greater detail below.

Notwithstanding the Advisory Panel's class I recommendation, on March 15, 1999, FDA published a proposal to reclassify all denture pads and cushions as class II. In support of this classification the agency stated:

> During the classification of the preamendments devices, the Dental Product Classification Panel identified as risks to health common to the use of certain denture accessories, complications resulting from an alteration of the vertical dimension of a patient's jaw and irritation of oral tissues. Since classification of these devices, the agency has developed a guidance document describing its present conclusions regarding procedures to minimize the risk of such complications. Because the agency believes that the information contained in this guidance document is adequate to control for the identified risks to health, the agency is proposing that the "OTC Denture Reliners, Repair Kits, and Partially Fabricated Denture Kits" be a special control for the following four devices: OTC denture cushion or pad (§ 872.3540), OTC denture reliner (§ 872.3560), OTC denture repair kit (§ 872.3570), and partially fabricated denture kit (§ 872.3600).

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[4] Comments of Brimms Inc, submitted to Docket No. 94N-0118, Preamendment Class III Devices: Strategy Document, August 3, 1994.

[5] Reclassification Petition of Brimms Inc., submitted to Docket No. 95N-0034/CCP, July 9, 1996.

64 Fed. Reg. at 12779.

FDA's explanation for its class II classification thus utterly failed to acknowledge its departure from the recommendation of the Advisory Panel or to provide any rationale for doing so.

## IV. THE DENTAL PRODUCTS ADVISORY COMMITTEE RECOMMENDED THAT OTC FLOW-FORMED SYNTHETIC DENTURE SURFACES BE CLASSIFIED AS CLASS I

On February 12, 1997, the Dental Products Advisory Panel met to consider two reclassification petitions for denture cushions: (1) a petition submitted by Brimms for Denturite®; (2) a petition submitted by Mentholatum for a soft plastic denture cushion. Brimms presented clinical study data to the Advisory Panel demonstrating that Denturite® (1) caused substantial improvement in denture stability and retention, (2) did not cause significant change in freeway space or phonation space, and (3) did not cause more than a slight increase in localized irritation, and that the device's labeling instructions were easy for the lay user to follow.[6] Brimms specifically addressed FDA's concern that denture cushions and pads could cause increased vertical dimension of occlusion which could result in bone resorption and formation and carcinomas:

> [T]he flowable nature of the material prevents the device from altering the vertical dimension of occlusion because it adapts to proper tissue apposition relative to the various tissue contours which results in varying thicknesses of the material. The net result is zero or a very minimal change in vertical dimension of occlusion or bite characteristics.
>
> The results of the clinical study supports this. As we have explained, the viscosity and set rate of the subject device assure that it will flow freely and not increase the vertical dimension of occlusion.[7]

Regarding the agency's concern about the effects of long-term irritation of tissues, Brimms stated:

> [W]e note that only one minor localized irritation was seen in a fraction of the clinical study participants. In a study conducted by Leco, et al. comparing tissue response to new dentures, professionally relined dentures, and denture fitted with temporary

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[6] Panel Meeting at 22-24.

[7] Id. at 25.

> cushions, comparable, if not higher incidence of local irritation were seen in all three groups.
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> The fact that local irritation is associated equally with new dentures, professionally relined dentures, and dentures fitted with temporary cushions suggests that it is the use of the dentures rather than any specific material which is the significant contributor.
>
> It must be noted that the continuous wear of hard-surfaced ill-fitting dentures is significantly more detrimental to the supporting oral tissues, causing rapid and excessive bone loss, papillary hyperplasia, inflammation, ulcers, epuli and possible tumors.[8]
>
> There was concurrence with this statement from among the Advisory Panel:
>
> There is no more risk and perhaps less risk with this device than wearing the dentures without the device. Therefore, I do not see any specific risk that the device brings about. The risks are greater if you don't wear the device, in my opinion.[9]
>
> After hearing the presentations from Brimms and Mentholatum, the Advisory Panel voted to classify Denturite® and the product manufactured by Mentholatum as class I devices.

## V. GENERAL CONTROLS ARE ADEQUATE TO ENSURE THE SAFETY AND EFFECTIVENESS OF DENTURITE®

At the Advisory Panel Meeting, Brimms asserted that proper labeling of Denturite® was necessary to ensure its safe use: "Labeling . . . is a principal means of controlling all risks. It is under such labeling conditions that the subject device has been marketed without unreasonable risk to the health of the patient for nearly 40 years."[10] Brimms further asserted that "the risks to health associated with the device are well-known and can readily be controlled through labeling and other class I controls."[11]

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[8] Id. at 26-27.

[9] Id. at 163 (Statement of Dr. Patters).

[10] Id. at 28.

[11] Id. at 32.

Advisory Panel members agreed that adequate labeling was key to ensuring the safe use of the product.[12] While there was discussion about whether special controls would be required to ensure proper labeling, a majority of the Advisory Panel concluded that adequate labeling could be ensured under class I, for example through labeling restrictions such as the one currently required under 21 C.F.R. § 801.405.[13] The Advisory Panel did not identify any risks from the device for which special controls would be required.

General controls are adequate to ensure the safety and effectiveness of Denturite®. Adequate directions for use can be ensured through labeling restrictions such as 21 C.F.R. § 801.405. Registration,[14] adverse event reporting,[15] and good manufacturing practice (GMP)[16] requirements, all of which are mandated for class I devices, will further ensure adequate protection of consumers. No risks have been identified for which special controls are required, thus class II classification is not warranted.

## VI. FDA'S PROPOSED LABELING INACCURATELY DESCRIBES THE RISK ASSOCIATED WITH THE DEVICE

FDA's Guidance Document for OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits incorporates the labeling currently required under 21 C.F.R. § 801.405:

> *Warning* – For temporary use only. Long term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until A Dentist Can Be Seen.[17]

This warning erroneously links the identified risks to health with use of denture cushions or pads. However, as was noted during the discussion by the Advisory Panel, these risks are in fact associated with wearing dentures -- in particular with wearing dentures that do not fit properly -- and may be reduced by wearing denture cushions or pads.[18] Thus, the labeling should be amended to reflect the actual source of the risk, for example by replacing the phrase "Long term use of this product" with "Long term use of improperly fitting dentures."

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[12] See generally Panel Meeting at 92-176.

[13] Id. at 96 (Statement of Dr. Jeffries) and 128 (Statement of Dr. Rubin).

[14] 21 C.F.R. Part 807.

[15] Id. Part 803.

[16] Id. Part 820.

[17] Center for Devices and Radiological Health, Guidance for Industry and Staff, OTC Denture Cushions, Pads, Reliners, Repair Kits, and Partially Fabricated Denture Kits, August 18, 1998, at 6.

[18] See note 9 supra.

The admonition that the product should be used "only until a dentist can be seen" also does not accord with the recommendations of the Advisory Panel. This warning implies an urgent health risk for which immediate medical attention is warranted. While there was agreement among Advisory Panel members that denture cushions should be used only temporarily and that consultation with a dentist to refit the dentures was the appropriate long term action, no Advisory Panel member expressed the opinion that failure to consult a dentist immediately would lead to adverse health consequences. The Advisory Panel requested the inclusion of a recommendation to FDA that the labeling include a maximum duration of use for the device of six weeks.[19] Brimms believes that this length of time is appropriate and urges FDA to amend the labeling to include a statement "Do not use for more than six weeks before consulting a dentist" in place of the current statement.

## VII. CONCLUSION

The data that Brimms has submitted to FDA on several occasions concerning Denturite® demonstrate the safety and effectiveness of the product. The Dental Products Advisory Panel voted to classify the device as class I, concluding that general controls are adequate to ensure the safety and effectiveness of Denturite®. FDA has articulated no basis for rejecting the Advisory Panel's recommendation. Brimms therefore urges FDA to revise its proposed rule and to classify Denturite-type denture cushions and pads as class I devices.

Respectfully submitted,

BRIMMS, INC.

Robert Berghash/gkj

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CEO

[19] Panel Meeting at 169 (Statement of Dr. Patters) and 176 (Statement of Dr. Greenspan).